

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TWINSTRAND BIOSCIENCES, INC. &
UNIVERSITY OF WASHINGTON,

Plaintiffs and
Counterclaim Defendants,

v.

GUARDANT HEALTH, INC.,

Defendant and
Counterclaim Plaintiff.

C.A. No. 21-1126-LPS

**PLAINTIFFS' REPLY BRIEF IN SUPPORT
OF THEIR PARTIAL MOTION TO DISMISS**

Dated: March 18, 2022

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In arguing that it has sufficiently pled its inequitable-conduct claims, Guardant's opposition simply restates its allegations that claim copying occurred and that the named individuals had a duty to inform the PTO of this alleged copying. But those allegations do not go to the deficiencies identified in Plaintiffs' opening brief, namely the absence of well-pleaded facts showing (i) why the withheld information is but-for material as to the issuance of the '699 and '951 patents, and (ii) that the named individuals intentionally withheld this information for the purpose of deceiving the PTO. In particular, Guardant posits that had the alleged copying been disclosed, interference proceedings would have been instituted. But Guardant does not point to a single alleged fact that could support why these interference proceedings would have resulted in the non-issuance of Plaintiffs' patent claims—Guardant's Counterclaims do not even make the conclusory assertion that this would be the outcome of any interference. As for specific intent, Guardant points to the duty of candor the inventors had to the PTO, but they do not plead any facts that these individuals disregarded this duty with the intent to deceive the PTO.

Similarly, Guardant's inventorship allegations are devoid of facts supporting the pertinent elements of inventorship. Instead of pleading facts alleging that Plaintiffs did not conceive of the subject matter in their patents, Guardant argued that it need not plead facts and that a bare assertion that the '699 and '951 patents do not list the correct inventors is sufficient. D.I. 43 at 13. But that is not the law. Finally, Section 135 does not provide a cause of action or defense for invalidity. Guardant does not—and cannot—present any controlling authority stating otherwise.

I. GUARDANT'S COUNTERCLAIMS FAIL TO MEET THE HEIGHTENED PLEADING STANDARD FOR INEQUITABLE CONDUCT

The parties agree that to sufficiently plead inequitable conduct based on claim copying, Guardant must plead facts leading to the plausible conclusion that (1) but-for the non-disclosure of the alleged claim copying to the PTO, the '699 and '951 patents would not have issued, and

(2) each named individual not only knew that this non-disclosure was material, but also that there was a “strong inference of fraudulent intent” to deceive the PTO. *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327–29, n.4 (Fed. Cir. 2009). Guardant’s opposition fails to show that its Counterclaims plead adequate facts establishing either of these elements.

A. Guardant’s allegations are devoid of facts that support a non-speculative inference of materiality.

In Guardant’s attempt to show it has pled *facts* sufficient to establish that the non-disclosure of the copying is material, it points to four—and only four—allegations, specifically:¹

1. The “failure to notify the PTO ‘constitutes disreputable or gross misconduct’ with specific citations to statutes and the Manual of Patent Examining and Procedure.” (D.I. 43 at 5);
2. The claims “would not have issued if [the named individuals] had notified the PTO of the copied claims.” (*id.* at 11);
3. The disclosure of the alleged claim copying “would have triggered an interference,” which Guardant characterizes as a “much more thorough and in-depth examination as to whether the claims of the [] Application were entitled to be issued...” (*id.* at 6, 10); and
4. There is one instance where claim copying was disclosed in which “no patent issued” (*id.* at 11).

None of the allegations support the necessary but-for showing required at this stage.

First, no weight should be afforded to Guardant’s allegation asserted in its Counterclaims that the alleged non-disclosure “constitutes disreputable or gross misconduct.” D.I. 43 at 5 (citing

¹ Despite alleging, without any factual support, that the alleged conduct here is egregious and *per se* material (D.I. 30, ¶¶ 261, 286), Guardant does not argue that its *per se* allegation is supported by facts. The Court therefore should give that allegation no weight in deciding this motion. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292–93 (Fed. Cir. 2011) (“Because neither mere nondisclosure of prior art references to the PTO nor failure to mention prior art references in an affidavit constitutes affirmative egregious misconduct....”).

D.I. 30, ¶¶ 257, 283). For starters, this allegation is nothing more than a legal conclusion, relying only on “statutes and the Manual of Patent Examining and Procedure”—not a well-pleaded fact. *Id.*; see also *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210–11 (3d Cir. 2009). Moreover, Guardant’s references to statutory provisions and the MPEP in its Counterclaims do not go to the issue of but-for materiality. Instead, at best, these citations show there was a duty to disclose. But alleging that one owes a duty of candor to the PTO is *not* the same as alleging that the supposedly withheld information is material. The existence of a duty to the PTO and materiality are separate inquiries. See *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1375, n.3 (Fed. Cir. 2008) (noting that not all omissions are material). To be sure, the Federal Circuit has held that a mere breach of the duty to disclose does not establish materiality. See *Therasense*, 649 F.3d at 1294 (stating the but-for requirement is absent from Rule 56, that “The PTO stated that Rule 56 ‘do[es] not define fraud or inequitable conduct,’” and the Federal Circuit “is not bound by the definition of materiality in PTO rules.” (internal citations omitted)).

Second, the Court should likewise give no weight to Guardant’s conclusory allegation that the ’699 and ’951 patents would not have issued based on the alleged omission of claim copying. This is not a *fact*; it is nothing more than a paraphrasing of the but-for element in its inequitable-conduct claims. See *Analog Devices, Inc. v. Xilinx, Inc.*, C.A. No. 19-2225, 2021 WL 466859, at *3 (D. Del. Feb. 9, 2021) (alleging “‘but for Mr. Levi’s material omission, the USPTO would not have granted one or more claims of the ’184 patent’ is insufficient to satisfy this [inequitable conduct] pleading standard”). Again, Guardant does not explain the “how” or “why” the alleged omission of claim copying would have affected the PTO’s decision to issue the ’699 and ’951 patents had it been aware of the alleged copying. See *Therasense*, 649 F.3d at 1291 (“in assessing the materiality of a withheld reference, the court must determine whether the

PTO would have allowed the claim if it had been aware of the undisclosed reference”).

Third, Guardant incorrectly insists that its allegation that an interference would have been triggered if claim copying had been disclosed is sufficient at this stage. This allegation fails for the basic reason that Guardant does not plead facts raising a plausible inference that UW would have lost such an interference or why that would have occurred.² D.I. 30, ¶¶ 262, 287. To be sure, that an interference would have been declared is itself implausible given that Guardant concedes that the alleged copied claims were later amended by UW. That fact is critical because interferences are declared only when a given patent application’s claims are in condition for allowance. D.I. 43 at 11. Therefore, the claims that are the subject of Guardant’s interference theory would never have been part of the interference. Lastly, Guardant does not point to any facts that plausibly suggest why an interference would have been declared (and Guardant would have prevailed in) given that UW’s patents are pre-AIA and Guardant’s patent and application are post-AIA.³

Fourth, Guardant’s allegation that “in the one instance...[the named individuals] disclosed claim copying [but] ‘no patent issued’” is false and legally irrelevant. *Id.* at 11. It is unquestionably false because the claims of the relevant application issued as U.S. Patent No. 11,242,562 on February 8, 2022, without ever being amended. D.I. 39-3, Ex. CC. And, even if the allegation were not plainly false, it is not enough to allege, as Guardant does, that the act of copying is improper. Instead, Guardant must plead facts showing why the alleged copying would

² Guardants’ Counterclaims do not even allege that the posited interference would have prevented Plaintiffs’ claims from issue. And in its opposition, Guardant only says that it is *possible* that the ’699 and ’951 patents lack written-description support in an interference. D.I. 43 at 11 (“Plaintiffs’ copied claims *may* be unsupported by the specification....”) (emphasis added).

³ Guardant does not challenge that UW’s patents are pre-AIA while Guardant’s patent and application are post-AIA filings. D.I. 43 at 11.

have stood in the way of the patents issuing. And it has simply failed to do that.

Finally, Guardant sidesteps several critical arguments that Plaintiffs advanced in their opening brief. Guardant does not dispute the fact that UW’s original claims changed before they issued. But, Guardant fails to explain why this fact does not make any intermediate act of copying irrelevant for purposes of whether the claims would have issued. Instead, it points to Section 135(b)’s requirement to inform the PTO of copying, but this again confuses the existence of a duty to disclose with the separate issue of materiality. D.I. 43 at 11–12.

B. Guardant has not pled facts that reasonably show specific intent to deceive.

Guardant has also failed to set forth well-pleaded facts that each named individual not only knew that this non-disclosure was material, but also that there was a “strong inference of fraudulent intent” to deceive the PTO. *Exergen*, 575 F.3d at 1327, n.4.

First, it is now undisputed that any alleged copying was not *exact* copying. D.I. 43 at 8, n.1. This fact is important because the duty to inform the PTO of claim copying under § 135 is triggered for claims that are the “same” or “substantially the same subject matter.” 35 U.S.C. § 135(b) (pre-AIA). Under the law, substantial similarity of claims is determined by a two-way test that considers whether the allegedly copied claims are anticipated or made obvious by the allegedly copied patent and vice-versa. *See Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1161 (Fed. Cir. 2006) (“two patents interfere only if...invention *A* either anticipates or renders obvious invention *B*...and...vice versa”). Because the claims here are not exact copies of Guardant’s claims, Guardant must plead facts that would give rise to a strong inference that the named individuals recognized that their claims, although not the same as Guardant’s, nevertheless satisfied the two-way test *and* chose to conceal this fact during prosecution to deceive the PTO. But Guardant has not pled such facts.

Second, Guardant not only fails to plead facts that would support a strong inference on

the intent prong, but it pled facts that undercut any such an inference. For example, Guardant’s ’822 patent was cited in an IDS during prosecution of the ’066 application. D.I. 30, ¶ 252. While Guardant is correct that this shows the named individuals knew of the ’822 patent, it completely guts any notion that they were engaged in an intentional effort to deceive the PTO—if the plan was to surreptitiously smuggle Guardant’s subject matter into UW’s patent, why cite the alleged source material to the PTO?⁴ Guardant similarly undercuts any strong inference of specific intent with its “pattern of copying claims” allegations. *See* D.I. 43 at 6–8. Guardant alleges five such instances but then concedes that in four instances the individuals cited the alleged source material for the copying in an IDS to the PTO. *Id.* Again, if there were a specific intent to deceive the PTO by concealing the copying, why did the individuals consistently cite that alleged source material to the PTO? Guardant does not say. And Guardant attempts to make hay of the “one instance” where the individuals informed the PTO of copying but no patent issued. D.I. 43 at 6, 11. The apparent inference is that the individuals learned a hard lesson: informing the PTO of copying will stand in the way of a patent issuing. But that is not what happened. As Plaintiffs pointed out in their opening brief, the ’305 application issued as U.S. Patent No. 11,242,562. D.I. 39 at 12, Ex. CC. Therefore, there is no reason to infer that anyone had specific intent to deceive the PTO by withholding information. If anything, the named individuals have a pattern of disclosing information to the PTO in accordance with their duty, when applicable.⁵

Insofar as Guardant believes it has pled that the named individuals “engaged in a pattern

⁴ This fact also undercuts the materiality elements. If there was something relevant about the ’822 patent that would have stood in the way of the ’699 patent issuing, it was cited in an IDS for the examiner to consider.

⁵ Insofar as Guardant relies on this instance to show that the individuals knew they possessed a duty to disclose, that does not itself create a strong inference that the same individuals intentionally disregarded that duty to deceive the PTO. *See Therasense*, 649 F.3d at 1290 (“In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference.”).

of copying claims and withheld the fact of that copying,” Guardant misses the mark. D.I. 43 at 7. Guardant alleges only that the applications “included at least one copied claim,” but does not identify which claim in each of these instances was supposedly copied. D.I. 30, ¶¶ 265, 290. Without facts underlying Guardant’s allegations of a “pattern” of copying, there can be no inference that the named individuals “made a deliberate decision to withhold” information with specific intent to deceive the PTO. *See Therasense*, 649 F.3d at 1290 (“In a case involving nondisclosure of information, ...evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference.” (citation omitted)); *Exergen*, 575 F.3d at 1328–29 (“a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual...withheld or misrepresented this information with a specific intent to deceive the PTO.”).

II. GUARDANT FAILS TO PLEAD A PLAUSIBLE IMPROPER INVENTORSHIP CLAIM

Whether or not Guardant’s Counts V and VI are directed to a derivation claim or an improper inventorship claim, Guardant has failed to plead any facts that either Guardant’s inventors conceived of the subject matter in UW’s patents or that the named inventors did not. Guardant instead relies heavily on *Belcher*, claiming that its allegations are “based on improper copying of claims from Guardant patents,” that it “need not plead facts regarding conception,” and in any case, its copying allegations concern conception. D.I. 43 at 13. Guardant is wrong.

A. Guardant misapprehends *Belcher*.

Guardant suggests that to survive a motion to dismiss, a claim of improper inventorship need only allege that the challenged patent names the wrong inventors. *Id.* (citing *Belcher Pharms., LLC v. Hospira, Inc.*, C.A. No. 17-775-LPS, 2019 WL 2503159, at *1 n.1 (D. Del. June 5, 2019)). That is incorrect. “Inventorship is a question of law...based on underlying facts.”

Univ. of Pittsburgh of Commonwealth Sys. of Higher Educ. v. Hedrick, 573 F.3d 1290, 1297 (Fed. Cir. 2009). Therefore, allegations that a patent names the wrong inventors, without more, plead only an ultimate legal conclusion that is insufficient to satisfy the pleading standards set forth in *Twombly* and *Iqbal*. *EMC Corp. v. Zerto, Inc.*, C.A. No. 12-956-GMS, 2014 WL 3809365, at *2 (D. Del. July 31, 2014).

To justify its insufficient pleading, Guardant relies on a footnote in *Belcher* that “[a] patent may be invalid simply because it names the wrong inventors.” D.I. 43 at 13 (citing 2019 WL 2503159, at *1 n.1). But in *Belcher*, the defendant filed a counterclaim alleging that the sole inventor named on the asserted patent “neither conceived of nor reduced to practice” the claimed subject matter. C.A. No. 17-775-LPS (D. Del.), D.I. 159, ¶ 100. The defendant also cited deposition testimony by the sole named inventor admitting that: (1) he “considered himself a ‘businessman, not a scientist’”; (2) he “made the decision to file the [asserted] patent and name himself inventor”; (3) his contribution to the invention was asking the pharmaceutical manufacturer to “evaluate formulations” with a specific pH; (4) he could not recall how instructions were communicated to the manufacturer; (5) he “had no recollection of ever even discussing with anyone ... the parameters for the...study that allegedly led to the development of a formulation that he asserts embodies the [asserted] patent claims”; and (6) the “experiments disclosed in the...patent were performed by unnamed ‘chemists’ at” the pharmaceutical manufacturer. *Id.*, ¶¶ 94–99.

Because the defendant pleaded sufficient *facts* challenging conception, the court denied a motion to dismiss the improper inventorship allegations.⁶ *Belcher*, 2019 WL 2503159, at *1.

⁶ The plaintiff in *Belcher* filed its motion to dismiss and supporting papers under seal. *See Belcher*, C.A. No. 17-775-LPS (D. Del.), D.I. 162, 163. Versions of these papers are not available on the public docket.

B. Guardant does not allege facts regarding conception similar to those in *Belcher*.

In contrast to the factual allegations in *Belcher*, Guardant does not identify a single fact capable of supporting a reasonable inference that either Dr. Talasaz or Dr. Eltoukhy, or both, conceived of the subject matter claimed in UW’s patents, or that the named inventors of the ’669 and ’951 patents did not. *See Burroughs Wellcome Co. v. Barr Lab’ys, Inc.*, 40 F.3d 1223, 1227–28 (Fed. Cir. 1994) (“Conception is the touchstone of inventorship”). Rather, Guardant’s claims rest on leaps of logic and its belief that certain proposed claim language submitted during the prosecution of the ’699 and ’951 patents (language that was later amended) allegedly bears some resemblance to claim language recited in either Guardant’s ’822 patent or in the ’427 application.

Guardant’s allegations, even if true, do not support a plausible improper inventorship claim because they rest on allegations of claim copying and similarity of language. They do not implicate whether or not the named inventors of the ’669 or ’951 patents—or even Drs. Talasaz or Eltoukhy—formed “a definite and permanent idea of the complete and operative invention” because Guardant fails to set forth any factual allegations regarding the conception and reduction to practice of UW’s patents. *REG Synthetic Fuels, LLC v. Neste Oil Oyj*, 841 F.3d 954, 962 (Fed. Cir. 2016).

C. Section 135(b) is a statute of repose that does not provide a cause of action.

Guardant’s Count V and Twelfth Affirmative Defense include an allegation that the Court should declare the ’699 patent unpatentable under pre-AIA § 135(b). Unambiguous legislative intent and controlling⁷ Federal Court precedent clearly establish § 135(b) as a statute

⁷ In addition to failing to cite any controlling precedent showing that § 135(b) is a proper defense under § 282, Guardant speculates that the court in *Chiron* “would have likely permitted the § 135 invalidity defense to proceed” had it been aware of the *Quantum* decision. D.I. 43 at 16. But *Quantum* was issued seven years *before* the *Chiron* decision. *Compare Quantum Corp. v.*

of repose, limiting the time the PTO has the authority to declare an interference. *Regents of Univ. of California v. Univ. of Iowa Rsch. Found.*, 455 F.3d 1371, 1376 (Fed. Cir. 2006) (collecting cases). Section 135, by its own terms, does not provide a basis for invalidity, nor is it an enumerated invalidity defense under 35 U.S.C. § 282. *Chiron*, 268 F. Supp. 2d at 1171. Guardant does not, and cannot, identify a single court that has recognized § 135(b) as a cause of action or basis for invalidity.

Guardant’s attempt to repurpose § 135 as an invalidity defense or cause of action is also unnecessary and inconsistent with its §§ 101 and 115 challenges. For example, Guardant suggests that it “will have no recourse” in this matter should the court dismiss its § 135 defenses. D.I. 43 at 16. Yet, Guardant also claims that Plaintiffs’ motion should be denied because they do not challenge the applicability of §§ 101 and 115. *Id.* at 4. Guardant further acknowledges that discovery on its §§ 101 and 115 defenses would “largely, if not completely, overlap with discovery” on a § 135 defense. *Id.* at 16.

In any event, Guardant’s §§ 101 and 115 challenges are improper. The proper vehicle for an improper inventorship claim over a pre-AIA patent is § 102(f). Sections 101 and 115 apply to patents subject to the AIA provisions of the Patent Act. Because UW’s patents are pre-AIA and § 135 does not grant the relief Guardant seeks, Guardant’s inventorship claims and defenses should be dismissed.

III. CONCLUSION

For the foregoing reasons, Guardant’s counterclaims, Counts V–VIII, and Guardant’s Fourth, Eighth, and Twelfth Affirmative Defenses should be dismissed.

Rodime, PLC, 65 F.3d 1577, 1584 (Fed. Cir. 1995), with *Chiron Corp. v. Genentech, Inc.*, 268 F. Supp. 2d 1148, 1171 (E.D. Cal. 2002).

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